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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,067	11/19/1999	BRIAN R. MURPHY	17634-000512	8148

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/444,067	Applicant(s) MURPHY ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-78,88-119,121,122,128-145 and 147-161* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-67,89,93-95,121,122,128-136,148,150 and 160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 68-78,88,90-92,96-119,137-145,147,149,151-159, and 161.

DETAILED ACTION

Status of the Claims

1. Claims 63-78,88-119,121,122,128-145 and 147-161 are currently pending in the present application. Claims 68-78,88,90-92,96-119,137-145,147,149,151 and 161 have been withdrawn from consideration. Claims 63-67, 89, 93-95, 121, 122, 128-136, 148, 150, and 160 are under examination to the extent that they read on the elected invention.

2. The claims under consideration were rejected in the prior action, the Final Rejection mailed on March 4, 2002. In the RCE filed in response on April 14, 2003, the Applicant cancelled previously pending, and rejected, claim 120, and amended claims 122, 128, 129, 130, and 131.

3. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

Double Patenting

4. **(Prior Rejection- Maintained)** Claim 131 was rejected over claims 23, 24, and 62 of co-pending application 09/291,894. The Examiner notes the Applicant's deferral of their response to the rejection. The rejection is therefore maintained.

5. **(New Rejection)** Claims 63, 65, 89, 93, 95,122-131, 133-136, 148, 150 and 160 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-8, 23, 26, 27, 29, 30, 36 59-64, and 69-71 of copending Application No. 09/611,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application include all of the limitations of the viral particles claimed in the present application. The claims of the copending application read on an RSV particles with a gene deletion of the M2 ORF2 gene, with or without other attenuating mutations and a deletion of the SH gene. The identified claims of the present application read on RSV particles with a gene deletion (i.e. one or more deletions), particles with a deletion of the SH gene (including particles with such a deletion in the presence of other deletions), with or without other attenuating mutations. Thus, the claims read on overlapping subject matter (RSV particles with a gene deletion, and with such a deletion plus other attenuating mutations).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection-Withdrawn)** Claims 128-131 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims were rejected for reading on vaccine compositions comprising the claimed recombinant RSV particles. The rejection was on the basis that the Applicant is not enabled for live RSV vaccines. In the RCE, Applicant amended the claims to read on immunogenic compositions, rather than on vaccines, comprising the RSV particles. In view of this amendment, and the fact administration of such compositions would raise an immune response, but may not necessarily be protective, the rejection is withdrawn.

8. **(New Rejection)** Claims 63-67, 89, 93-95, 121, 122, 128-136, 148, 150, and 160 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on embodiments of the claimed chimeric RSV wherein the virus comprises a RNA polymerase elongation protein. Thus, the claim as written encompasses a generic class of chimeric RSV virus, each of which may contain any RNA polymerase elongation factor. The specification does not provide adequate written description support for the full scope of these generic claims.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Also relevant to the discussion are the following excerpts from the case of In re Borkowski and Van Venrooy, 164 USPQ 642, (CCPA 1970). In describing the appropriate grounds for a claim rejection when the claim exceeds the scope of the disclosure, the court stated the following:

> *... a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.* (Excerpt from164 U.S.P.Q. at 645)

and;

> *... if the "enabling" disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the second paragraph of §112; rather, the claim is based on an insufficient disclosure 4 (§112, first paragraph) and should be rejected on that ground. See In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963); In re Kamal, 55 CCPA 1409, 398 F.2d 867, 158 USPQ 320 (1968); and In re Wakefield, 164 USPQ (PA 8192), decided concurrently herewith. Thus, just as a claim which is of such breadth that it reads on subject matter disclosed in the prior art is rejected under §102 rather than under the second paragraph of §112, a claim which is of such breadth that it reads on subject matter as to which the specification is not "enabling" should be rejected under the first paragraph of §112.* (Excerpt from 164 U.S.P.Q. at 646).

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would

recognize from the specification the scope of what is being claimed. However, a disclosure will also support the claims in the absence of examples if the description would enable one in the art to practice the invention without such guidance.

In the present case, the applicant has disclosed only a single example of a RNA polymerase elongation factor- the M2 ORF 1 protein of RSV. See e.g., pages 14, lines 6-9; and page 64, lines 3-7. Although the specification states that a "substantially equivalent transcription elongation factor" may be used instead of the M2 ORF1, neither the description nor the examples in the application provide any indication of what such substantially equivalent factors may be. Furthermore, the M2 ORF 1 elongation factor protein has been disclosed in the art as necessary for the replication of infectious RSV particles. See e.g., Collins et al, PNAS 92:11563-67 (of record in the IDS filed July 27, 2000). The Collins reference does not however, disclose that any elongation factor would suffice in the place of the M2-1 protein. Further, the application at hand does not provide any examples, or guidance, to either show that other elongation factors would be operative, or to show which elongation factors would be considered as operative homologues. Without such examples, or some identification of the M2 ORF1 structure that is necessary to its operation, one in the art wishing to practice the invention has no indication as to what, if any, other proteins may be used as elongation factors in the claimed virus. In view of the lack of description for any RNA polymerase elongation factor other than the M2 ORF1, the claims are rejected for exceeding the scope of descriptive support provided by the specification.

9. **(New Rejection)** Claims 63-67, 89, 93-95, 121, 122, 128-136, 148, 150, and 160 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

an isolated infectious chimeric RSV wherein the virus comprises the M2 (ORF1) RNA polymerase elongation factor, does not reasonably provide enablement for viruses containing any RNA polymerase elongation factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

A claim is commensurate in scope with the enablement when the applicant has provided sufficient disclosure to enable one skilled in the art to practice the claimed invention without undue experimentation. In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988). There must be a "reasonable correlation" between the scope of enablement and the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Such correlation requires "sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." See, In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (CAFC 1991) No such guidance is provided in the present case.

Both the present application (page 64, lines 3-20), and the art relevant to the claimed invention (see, Collins et al., supra), indicates that the M2 ORF1 protein is one of the minimal proteins necessary for an infectious RSV. Although the application does state that substantial equivalents of this identified protein may be used (pages 52-53), it does not identify any characteristic or examples which one of ordinary skill in the art could use as guides to identify such equivalents. Further, the combined teachings of the specification, indicating that only

substantial equivalents of the M2 ORF1 protein may be used, and the art, teaching that an operative M2 ORF1 protein is necessary for an operative chimeric RSV (Collins et al., PNAS 92:11563-11567), indicate that only a specific subclass of RNA polymerase elongation factors may be used in the invention. As the application has provides no examples or other indication as to what proteins fall within this subclass, other than the M2 ORF1 protein itself, the application has not provided an enabling disclosure corresponding to the full scope of the rejected claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **(Prior Rejection- Withdrawn)** Claim 120 was rejected in the prior action under 35 U.S.C. 112, second paragraph for being indefinite. As this claim has been cancelled from the application, the rejection is withdrawn.

12. **(New Rejection)** Claim 94 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim depends from claim 1, which has been cancelled from the application. As this claim depends from a cancelled claim, it is not clear what the claim is describing.

For the purposes of forwarding the prosecution of the case, it is being assumed that the claim was intended to depend from either claim 63, or from claim 89 for the purposes of the other rejections of this claim under 35 U.S.C. §§ 112, 102, and/or 103.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

14. Claims 63, 65, 89, 93-95,122-131, 133-136, 148, 150 and 160 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Both the present application, and copending application 09/611,829 claim overlapping subject matter as identified above. However, the named inventors of the two applications are not the same.

Claim Rejections - 35 USC § 103

15. **(Prior Rejection- Maintained)** Claims 63-67, 89. 93-95, 121, 128, 131-136, 148, and 150 were rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al., PNAS 92:11563-67. Further, claims 122, 129, and 130, and claim 160, were rejected over Collins in view of, respectively, Randolph et al., EPA 0 567 100, and Klein et al., WO 93/14207. The rejected claims describe recombinant infections RSV with a deletion of the RSV SH gene. The Applicant traverses this rejection on the grounds that the Examiner has not provided a practical motivation for one of ordinary skill in the art to make the claimed recombinant RSV. In this argument, the Applicant depicts the Examiner's statements in the prior action as withdrawal of the original characterization of the reference. The Examiner agrees in part with the Applicant's conclusion. The Collins article does not teach that an RSV with a SH gene deletion would be an

effective immunogenic composition. However, the reference does teach the development of such an RSV for the purpose of identifying the function of the protein. Page 11566, column 1. Further, in demonstrating how to make the RSV particles using minigenomes, it would have been obvious to those in the art to make SH gene deficient RSV particles using similar techniques to incorporate the SH protein into the particles if such were found necessary in the studies. Thus, the article does teach how to make the particles.

The Applicant also argues that, as part of establishing a practical motivation under 35 U.S.C. 103, the Examiner must show that the reference "must also reasonably forecast the properties that the skilled artisan would expect this new compound or compositions to have..." This is not wholly accurate. The Examiner need only show that those in the art could reasonably forecast the properties of the composition related to the motivation for making it. The Examiner need not show that those in the art would have known of all of the properties of the composition. In this case, the motivation for making the deletion mutant would be to study the function of the SH gene and protein. Thus, the reference teaches a reason for making the virus that does not involve a reasonable expectation in the immunogenic or replicative properties of the recombinant virus. Rather, the identified properties identified by the Applicant as unknown are the very properties suggested by the article for study. Page 11566, column 2. Once made, the properties of the recombinant virus are inherent to the composition. Thus, the Examiner is not persuaded by the Applicants arguments regarding the lack of motivation. Furthermore, because the reference specifically indicates that these deletion mutants should be made and tested for infectivity and pathogenicity in experimental animals, the reference also renders obvious the formulation of the virus into immunogenic compositions for those purposes.

However, while the Applicant's traversal is not persuasive regarding the rejected claims generally, it is noted that, because the effects of the SH gene deletion would not be known, there is no motivation from the Collins reference to combine the mutation with other attenuating mutations, and therefore no motivation to combine Collins with the Klein reference (teaching multimeric hybrid genes). Thus, the rejection is withdrawn over claims 89, 93-95, 148, 150, and 160. Claims 63-67, 121, 122, 128, 129-136 remain under rejection as described above, and in the prior action.

16. **(New Rejection)** Claims 63-67, 89, 93-95, 121, 122, 128-136, 148, 150, and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al., U.S. 6,264,957. This patent teaches infectious RSV comprising a genome or antigenome, the N, P, L, and M2 ORF 1 proteins. See e.g., claim 1. Collins further teaches that the SH protein can be studied by the ablation or mutation of SH gene expression, which would include partial or complete gene deletions, and that partial gene deletions of the SH gene could be used to make attenuated RSV. Column 9, lines 35-41, and column 10, lines 45-48, respectively. The patent also teaches that various attenuating mutations may be combined to reach an appropriate level of virus attenuation. Col. 10, lines 11-19. The patent also teaches immunogenic compositions of the virus, including the dosage, and the inclusion of antigens from multiple RSV strains or from other virus, including PIV. Columns 11-12. Thus, the patent teaches all of the various limitations of the claimed RSV particles, and would have rendered any one of them obvious to those or ordinary skill in the art.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
June 30, 2003

James C. Housel

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